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Roundup on Cosmetic Dermatology

2009



TOPIC HIGHLIGHTS:

- 2 Update on Laser Resurfacing, Fillers, and Botulinum Toxin
- 5 Managing Fat and Cellulite: Current State of the Field
- 8 Avoiding Dermal Filler Pitfalls Begins With a Mirror
- 10 Single Laser Tx Reduced Perioral Wrinkles
- 10 Fractional Laser Therapy Found Effective for Hands

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Update on Laser Resurfacing, Fillers, and Botulinum Toxin



David J. Goldberg, M.D., J.D.

The field of cosmetic dermatology has evolved on several fronts in recent years. Three areas that have attracted considerable attention are laser fractional resurfacing, fillers, and botulinum toxin.

Fractional resurfacing has taken standard ablative lasers and brought them into the 21st century with technologic modifications and enhancements that give cosmetic dermatologists the tools to achieve dynamic results with respect to skin rejuvenation and skin tightening. Moreover, the results can be achieved with minimal risk to the patient.

Carbon dioxide (CO₂), erbium yttrium aluminium garnet (YAG), and erbium yttrium scandium gallium garnet (YSGG) lasers all have models developed for fractional resurfacing. Fractionated delivery of laser energy has greatly reduced the amount of skin surface area that must be treated to achieve the desired results. Older lasers treated 100% of the skin surface in a flat, two-dimensional orientation. Fractional lasers treat about 60% of the skin surface in a vertically oriented approach to ablation.¹

During a treatment session, a fractional laser creates millions of microscopic holes in the skin, involving both the epidermis and superficial dermis. However, the lasers also offer the capability to penetrate to a depth greater than 1 mm, which has been shown to achieve long-lasting benefits in terms of skin tightening and rejuvenation. The lasers give cosmetic dermatologists unprecedented capability to tailor the treatment and the results to the individual needs of a patient.

From an anatomic and physiologic perspective, the laser light passes through the skin surface and is preferentially absorbed by the water in the age- and environment-damaged collagen beneath the surface. The process enables the removal of very fine layers of skin, diminishing wrinkles and other unwanted textures. As new cells form during the healing process, the wrinkled and damaged skin is replaced by skin that is smoother, softer, and younger looking. Fractional laser rejuvenation not only removes wrinkles and evens skin tone, but also instigates the growth of new collagen.²

The machines can be used to achieve overall improvement in skin texture or targeted to the treatment of isolated areas, including the hands, chest, and neck.

Fractional lasers provide consistent, predictable results controlled by the operator and requires less recovery time compared with more invasive procedures used to achieve skin rejuvenation. Depending upon the type of procedure performed, the recovery time can vary from a few days to a little more than a week.

Few areas of cosmetic dermatology can match the filler field with its ongoing research and development. The filler market has undergone rapid expansion in the past few years, challenging the clinicians' ability to remain abreast of the latest developments and newest products that have become available. Expansion of the filler market increases the likelihood that a patient can find the right product to meet specific needs and goals.

During the past year, a new porcine collagen filler has become available in the United States, representing an important addition to the options for filling wrinkles.³

Several other new fillers will likely become available over the course of the next year. Research continues to produce new candidate fillers at a steady pace, particularly in the area of hyaluronic acid fillers. Moreover, several fillers have been

Continued on page 6

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First home.

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For your first-time retinoid patients, RENOVA delivers retinoid efficacy with less irritation.¹



BASELINE



24 WEEKS

All photographs are completely unretouched. Results are after 24 weeks' treatment with RENOVA 0.02% and a comprehensive skin care program including sun protection. Results may vary.



RENOVA 0.02% is indicated as an adjunctive agent for use in the mitigation (palliation) of fine facial wrinkles in patients who use comprehensive skin care and sunlight avoidance programs. RENOVA 0.02% does not eliminate wrinkles, repair sun-damaged skin, reverse photoaging, or restore more youthful or younger skin. The safety and efficacy of using RENOVA 0.02% daily for greater than 12 months have not been established. RENOVA 0.02% is proven effective on lightly pigmented skin, Fitzpatrick skin types I, II, and III. Do not use RENOVA 0.02% if the patient is taking drugs known to be photosensitizers, pregnant, attempting pregnancy, or nursing. RENOVA 0.02% is a dermal irritant. Almost all patients experience skin reactions, including dryness, peeling, burning/stinging, erythema, and itching. In some patients, this may be severe.

Please see Brief Prescribing Information on the next page.

1. Nyrady J, Grossman R. Evaluation of the cumulative irritation potential of tretinoin: review of 2 clinical studies. *Cosmetic Dermatol.* 2002;15(7):33-36. RENOVA is a registered trademark of OrthoNeutrogena™. © 2008 OrthoNeutrogena 08DD0147 8/08 Printed in USA

RENOVA[®]

(tretinoin cream) 0.02%



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FOR TOPICAL USE ON THE FACE. NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.

Brief Summary

RENOVA (tretinoin cream) 0.02% contains the active ingredient tretinoin in a cream base.

IMPORTANT NOTE – This information is a **BRIEF SUMMARY** of the complete prescribing information provided with the product and therefore should not be used as the basis for prescribing the product. This summary was prepared by deleting from the complete prescribing information certain text, tables, and references. The physician should be thoroughly familiar with the complete prescribing information before prescribing the product.

INDICATIONS AND USAGE:

(To understand fully the indication for this product, please read the entire **INDICATIONS AND USAGE** section of the labeling.)

RENOVA (tretinoin cream) 0.02% is indicated as an adjunctive agent (see second bullet point below) for use in the mitigation (palliation) of fine facial wrinkles in patients who use comprehensive skin care and sun/avoidance programs. **RENOVA DOES NOT ELIMINATE WRINKLES, REPAIR SUN-DAMAGED SKIN, REVERSE PHOTOAGING, or RESTORE MORE YOUTHFUL or YOUNGER SKIN.** In double-blinded, vehicle-controlled clinical studies, many patients in the vehicle group achieved desired palliative effects on fine wrinkling of facial skin with the use of comprehensive skin care and sun/avoidance programs including sunscreens, protective clothing, and non-prescription emollient creams.

- RENOVA 0.02% has NOT DEMONSTRATED A MITIGATING EFFECT on significant signs of chronic sun/avoidance exposure such as coarse or deep wrinkling, tactile roughness, mottled hyperpigmentation, lentiginosities, telangiectasia, skin laxity, keratinocytic atypia, melanocytic atypia, or dermal elastosis.
- RENOVA should be used under medical supervision as an adjunct to a comprehensive skin care and sun/avoidance program that includes the use of effective sunscreens (minimum SPF of 15) and protective clothing.
- Patients with visible actinic keratoses and patients with a history of skin cancer were excluded from clinical trials of RENOVA 0.02%. Thus the effectiveness and safety of RENOVA 0.02% in these populations are not known at this time.
- Neither the safety nor the effectiveness of RENOVA for the prevention or treatment of actinic keratoses or skin neoplasms has been established.
- Neither the safety nor the efficacy of using RENOVA 0.02% daily for greater than 52 weeks has been established, and daily use beyond 52 weeks has not been systematically and histologically investigated in adequate and well-controlled trials. (See **WARNINGS** section.)

CONTRAINDICATIONS:

This drug is contraindicated in individuals with a history of sensitivity reactions to any of its components. It should be discontinued if hypersensitivity to any of its ingredients is noted.

WARNINGS:

- RENOVA 0.02% is a dermal irritant, and the results of continued irritation of the skin for greater than 52 weeks in chronic use with RENOVA are not known. There is evidence of atypical changes in melanocytes and keratinocytes and of increased dermal elastosis in some patients treated with RENOVA 0.05% for longer than 48 weeks. The significance of these findings and their relevance for RENOVA 0.02% are unknown.
- RENOVA should not be administered if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the possibility of augmented phototoxicity.

Exposure to sunlight (including sunlamps) should be avoided or minimized during use of RENOVA because of heightened sunburn susceptibility. Patients should be warned to use sunscreens (minimum SPF of 15) and protective clothing when using RENOVA. Patients with sunburn should be advised not to use RENOVA until fully recovered. Patients who may have considerable sun exposure, e.g., due to their occupation, and those patients with inherent sensitivity to sunlight should exercise caution when using RENOVA and follow the precautions outlined in the Patient Package Insert.

RENOVA should be kept out of the eyes, mouth, angles of the nose, and mucous membranes. Topical use may cause severe local erythema, pruritus, burning, stinging, and peeling at the site of application. If the degree of local irritation warrants, patients should be directed to use less medication, decrease the frequency of application, discontinue use temporarily, or discontinue use altogether and consider additional appropriate therapy.

Tretinoin has been reported to cause severe irritation on eczematous skin and should be used only with caution in patients with this condition.

Application of larger amounts of medication than recommended has not been shown to lead to more rapid or better results, and marked redness, peeling, or discomfort may occur.

PRECAUTIONS:

General: RENOVA should be used only as an adjunct to a comprehensive skin care and sun/avoidance program. (See **INDICATIONS AND USAGE** section.)

If a drug sensitivity, chemical irritation, or a systemic adverse reaction develops, use of RENOVA should be discontinued.

Weather extremes, such as wind or cold, may be more irritating to patients using tretinoin-containing products.

Information for Patients: See Patient Package Insert

Drug Interactions: Concomitant topical medications, medicated or abrasive soaps, shampoos, cleansers, cosmetics with a strong drying effect, products with high concentrations of alcohol, astringents, spices or lime, permanent wave solutions, electrolysis, hair depilatories or waxes, and products that may irritate the skin should be used with caution in patients being treated with RENOVA because they may increase irritation with RENOVA.

RENOVA should not be administered if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the possibility of augmented phototoxicity.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

In a 91-week dermal study in which CD-1 mice were administered 0.017% and 0.035% formulations of tretinoin, cutaneous squamous cell carcinomas and papillomas in the treatment area were observed in some female mice. These concentrations are near the tretinoin concentration of this clinical formulation (0.02%). A dose-related incidence of liver tumors in male mice was observed at those same doses. The maximum systemic doses associated with the 0.017% and 0.035% formulations are 0.5 and 1.0 mg/kg/day. These doses are 10 and 20 times the maximum human systemic dose, when adjusted for total body surface area. The biological significance of these findings is not clear because they occurred at doses that exceeded the dermal maximally tolerated dose (MTD) of tretinoin and because they were within the background natural occurrence rate for these tumors in this strain of mice. There was no evidence of carcinogenic potential when 0.025 mg/kg/day of tretinoin was administered topically to mice (0.5 times the maximum human systemic dose, adjusted for total body surface area). For purposes of comparisons of the animal exposure to systemic human exposure, the maximum human systemic dose is defined as 1 gram of 0.02% RENOVA applied daily to a 50 kg person (0.004 mg tretinoin/kg body weight).

Studies in hairless albino mice suggest that con-

current exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB and UVA light from a solar simulator. This effect has been confirmed in a later study in pigmented mice, and dark pigmentation did not overcome the enhancement of photocarcinogenesis by 0.05% tretinoin. Although the significance of these studies to humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

The mutagenic potential of tretinoin was evaluated in the Ames assay and in the *in vivo* mouse micronucleus assay, both of which were negative.

In dermal Segment I fertility studies in rats, slight (not statistically significant) decreases in sperm count and motility were seen at 0.5 mg/kg/day (20 times the maximum human systemic dose adjusted for total body surface area), and slight (not statistically significant) increases in the number and percent of nonviable embryos in females treated with 0.25 mg/kg/day (10 times the maximum human systemic dose adjusted for total body surface area) and above were observed. A dermal Segment III study with RENOVA has not been performed in any species. In oral Segment I and Segment III studies in rats with tretinoin, decreased survival of neonates and growth retardation were observed at doses in excess of 2 mg/kg/day (83 times the human topical dose adjusted for total body surface area).

Pregnancy:

Teratogenic effects: Pregnancy Category C.

ORAL tretinoin has been shown to be teratogenic in rats, mice, rabbits, hamsters, and subhuman primates. It was teratogenic and fetotoxic in Wistar rats when given orally or topically in doses greater than 1 mg/kg/day (42 times the maximum human systemic dose normalized for total body surface area). However, variations in teratogenic doses among various strains of rats have been reported. In the cynomolgus monkey, which, metabolically, is closer to humans for tretinoin than the other species examined, fetal malformations were reported at doses of 10 mg/kg/day or greater, but none were observed at 5 mg/kg/day (417 times the maximum human systemic dose adjusted for total body surface area), although increased skeletal variations were observed at all doses. A dose-related increase in embryolethality and abortion was reported. Similar results have also been reported in pigtail macaques.

TOPICAL tretinoin in animal teratogenicity tests has generated equivocal results. There is evidence for teratogenicity (shortened or kinked tail) of topical tretinoin in Wistar rats at doses greater than 1 mg/kg/day (42 times the maximum human systemic dose adjusted for total body surface area). Anomalies (humerus: short 13%, bent 6%, os parietal incompletely ossified 14%) have also been reported when 10 mg/kg/day was dermally applied.

There are other reports in New Zealand White rabbits administered doses of greater than 0.2 mg/kg/day (17 times the maximum human systemic dose adjusted for total body surface area) of an increased incidence of domed head and hydrocephaly, typical of retinoid-induced fetal malformations in this species.

In contrast, several well-controlled animal studies have shown that dermally applied tretinoin may be fetotoxic, but not overtly teratogenic, in rats and rabbits at doses of 1.0 and 0.5 mg/kg/day, respectively (42 times the maximum human systemic dose adjusted for total body surface area in both species).

With widespread use of any drug, a small number of birth defect reports associated temporally with the administration of the drug would be expected by chance alone. Thirty human cases of temporally-associated congenital malformations have been reported during two decades of clinical use of another formulation of topical tretinoin (Retin-A). Although no definite pattern of teratogenicity and no causal association has been established from these cases, 5 of the reports describe the rare birth defect category holoprosencephaly (defects associated with incomplete midline development of the forebrain). The significance of

these spontaneous reports in terms of risk to the fetus is not known.

Non-teratogenic effects:

Dermal tretinoin has been shown to be fetotoxic in rabbits when administered 0.5 mg/kg/day (42 times the maximum human systemic dose normalized for total body surface area). Oral tretinoin has been shown to be fetotoxic, resulting in skeletal variations and increased intrauterine death, in rats when administered 2.5 mg/kg/day (104 times the maximum human systemic dose adjusted for total body surface area).

There are, however, no adequate and well-controlled studies in pregnant women. RENOVA should not be used during pregnancy.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Since many drugs are excreted in human milk, mitigation of fine facial wrinkles with RENOVA 0.02% may be postponed in nursing mothers until after completion of the nursing period.

Pediatric Use: Safety and effectiveness in patients less than 18 years of age have not been established.

Geriatric Use: In clinical studies with RENOVA 0.02%, patients aged 65 to 71 did not demonstrate a significant difference for improvement in fine wrinkling when compared to patients under the age of 65. Patients aged 65 and over may demonstrate slightly more irritation, although the differences were not statistically significant in the clinical studies for RENOVA 0.02%. Safety and effectiveness of RENOVA 0.02% in individuals older than 71 years of age have not been established.

ADVERSE REACTIONS:

(See **WARNINGS** and **PRECAUTIONS** sections.)

In double-blind, vehicle-controlled studies involving 339 patients who applied RENOVA 0.02% to their faces, adverse reactions associated with the use of RENOVA were limited primarily to the skin. Almost all patients reported one or more local reactions such as peeling, dry skin, burning, stinging, erythema, and pruritus. In 32% of all study patients, skin irritation was reported that was severe, led to temporary discontinuation of RENOVA 0.02%, or led to use of a mild topical corticosteroid. About 7% of patients using RENOVA 0.02%, compared to less than 1% of the control patients, had sufficiently severe local irritation to warrant short-term use of mild topical corticosteroids to alleviate local irritation. About 4% of patients had to discontinue use of RENOVA because of adverse reactions.

Approximately 2% of spontaneous post-marketing adverse event reporting for RENOVA 0.05% were for skin hypo- or hyperpigmentation. Other spontaneously reported adverse events for RENOVA 0.05% predominantly appear to be local reactions similar to those seen in clinical trials.

OVERDOSAGE:

Application of larger amounts of medication than recommended has not been shown to lead to more rapid or better results, and marked redness, peeling, or discomfort may occur. Oral ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of Vitamin A.

Rx only.



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U.S. Patents 4,603,146 and 4,877,805

Managing Fat and Cellulite: Current State of the Field



Christopher B. Zachary,
F.R.C.P., M.B.B.S.

Though often discussed together, fat and cellulite represent two distinct types of cellular mass. As such, different health considerations and management options should enter into discussions between clinicians and their patients.

Any discussion of excess adiposity or obesity must begin with an emphasis on the role and value of diet, exercise, and lifestyle changes. Physicians have an obligation to encourage and assist patients in the adoption of practices that can improve patient health and reduce morbidity, as well as to improve physical appearance.

The patient's health must remain foremost in the assessment of an individual for cosmetic procedures involving the removal of adipose tissue. Before entering into a discussion about cosmetic procedures, the physician should perform a thorough medical history and physical examination to make sure that the patient is fit enough for a procedure.

Clinicians and their patients also must keep in mind that cosmetic procedures are designed for the removal of localized fat deposits that resist the effects of weight loss and exercise. Cosmetic procedures cannot replace weight loss for patients who are overweight or morbidly obese. Laparoscopic banded gastroplasty and other surgical procedures for obesity can dramatically change a patient's life. That point should not be confused with procedures to remove specific types of localized adiposity.

Standard tumescent anesthesia remains the most appropriate and effective treatment of localized fat collection, often characterized by colloquial expressions such as "saddle bags" and "love handles." Use of tumescent anesthetics to facilitate fat removal has a long history in cosmetic procedures and has a large volume of support in basic and clinical science.¹

The technique effectively removes fat deposits with minimal bleeding, bruising, and patient discomfort.

Laser lipolysis continues to attract a following in cosmetic dermatology, but one questions whether the technique truly achieves the results and overall success attributed to it.^{2,3} The technology has evolved from a good model. However, a relative paucity of basic science underlies the clinical application, making results and overall success difficult to interpret.

Laser lipolysis provides some skin tightening along with fat removal. Whether the skin tightening is superior to what can be achieved with tumescent anesthesia remains debat-

able. Some proponents have suggested that laser lipolysis makes tissue sculpting easier to accomplish. However, traditional liposuction with cannulas can provide the same benefits.

Currently, my assessment is that laser lipolysis costs much more and takes more time to perform, compared with tumescent anesthesia, and the benefits are questionable.

In contrast to adiposity, it has been argued that cellulite evolves from a structural problem of the fibroseptae, a concept challenged by others, which tends to be more vertically oriented in women and obliquely oriented in men. The difference in orientation has been evaluated and confirmed with various imaging techniques.⁴

Cellulite occurs predominantly in women, although androgen-deficient men and patients with prostate cancer treated with hormonal therapy also are prone to develop the tissue.

Several myths surround the development and treatment of cellulite. One myth is that obesity aggravates cellulite. Little evidence in the medical literature supports that contention. Another myth is that weight loss will improve cellulite. Given the different evolutionary paths of cellulite and adipose tissue, weight loss is unlikely to have a beneficial effect on cellulite, and little evidence supports that view.

A third myth is that liposuction can be used to treat cellulite. Some evidence supports that position, but far more scientific evidence argues against the value of liposuction for managing cellulite. In fact, I think liposuction has the potential to cause harm when used to treat cellulite.

Numerous therapies can temporarily improve the appearance of cellulite. Examples include Triactive, VelasMOOTH, and SmoothShapes.⁵ I liken the effects of these treatments to a haircut. So long as the patient understands that the benefits are temporary, these interventions have a role in the treatment of cellulite.

Several cosmetic procedures have demonstrated the potential to achieve long-term beneficial effects on cellulite. Any technique or procedure that thickens the dermis or induces subdermal fibrosis is likely to improve the appearance of cellulite. For example, cellulite does not occur in patients with localized scleroderma; the condition is accompanied by a thickening of the dermis

One intervention that could induce long-term changes in cellulite is cryolipolysis (Zeltiq), which has been demonstrated to remove fat cells and also induce superficial fibrosis in the skin. While no such claim has been made by the company, any procedure that thickens the dermis or causes an increase in upper fat fibrosis might prevent the herniation of fat into the dermis and thus the appearance of cellulite. The concept of cryolipolysis is derived from the clinical observation of cold induced neonatal fat atrophy.⁶

Other technologies offering promise for long-term changes

Continued on page 6

Update on Laser

Continued from page 2

available in Europe for some time and eventually could find their way to the US market.

Despite the large and growing number of fillers, they all fall into one of three broad categories based on their permanence:

► **Six months or less.** This category includes softer and finer bioengineered collagen and several types of hyaluronic acid-based compounds. Short-duration fillers often are used to treat smile lines and manage various types of wrinkles. Patients with no prior exposure to fillers might prefer a short-duration product to assess the cosmetic effects before deciding on a more lasting solution.

► **Six months to eighteen months.** Products in this category include the more robust hyaluronic acid fillers, products containing calcium hydroxyapatite (CaHA), and fillers based on poly-L-lactic acid (PLLA). CaHA products are ideally suited for the treatment of smile lines and for volume augmentation. PLLA primarily is a volume enhancer, producing a gradual effect over time rather than immediately. This category also includes porcine collagen, which was approved in the past year, and bovine collagen. Porcine collagen already has a history in clinical applications, most notable in the manufacture of heart valves. The product has a consistency and softness similar to that of human collagen. Proven compatibility with human tissues may obviate the need for skin testing, which is required for bovine collagen and has contributed to its declining use in the United States.

► **Permanent.** The only approved product in this category is an injectable gel filler consisting of synthetic microspheres suspended in bovine collagen. The microspheres are nonresorbable, which accounts for the lasting effect. Although the product is described as permanent, patients will require periodic supplementary treatments as their wrinkle lines deepen with age. Unfortunately, the company marketing this filler in the United States has filed for bankruptcy. It is expected that eventually the filler will once again be available.

Long-term and permanent fillers appeal to patients who have experience with fillers, who know what to expect in terms of results, and who are comfortable with the risk-benefit ratio of the products.

Use of botulinum toxin continues to evolve after more than a decade of use in cosmetic dermatology. Common uses include treatment of wrinkle lines around the eyes and to fill dynamic lines and furrows on the forehead, although the injections also work well as treatment for prominent neck bands or cords as well as for wrinkling around the upper lip. Many patients like botulinum toxin treatment because of its rapid effects, which usually are evident within 3 to 5 days after injection. Botulinum toxin often is used in combination with other filler materials to enhance the results.

Research aimed at improving botulinum toxin has been ongoing for some time, and several new products could become available in the near future, including some that could become available during 2009. ■

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Managing Fat and Cellulite

Continued from page 5

in cellulite are monopolar radiofrequency energy and ultrasound. Several devices have been developed to induce a localized, heat-induced chronic inflammatory process with associated apoptosis and a fibrotic reaction in the superficial fat tissues, leading to the tightening of deeper skin layers. This tightening should result in amelioration of the appearance cellulite. None of these devices has approval by the US Food and Drug Administration (FDA) for the permanent reduction of cellulite.

In summary, adiposity and cellulite are two distinct problems with differing etiologies. As such, they require different approaches to treatment. Patient health should be foremost in the cosmetic dermatologist's considerations when evaluating a patient for the removal of localized fat accumulation. Cosmetic procedures are not for the treatment of obesity.

Multiple interventions have been developed for the treatment of localized fat deposits and cellulite. Some have shown promise for accomplishing cosmetic objectives, but many others have not. Cosmetic dermatologists should stay abreast of developments in the field to make informed decisions about the application of technology to the treatment of adiposity and cellulite. ■

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Avoiding Dermal Filler Pitfalls Begins With a Mirror

As part of her pretreatment consultation before providing dermal fillers, Dr. Ranella Hirsch hands a mirror to her patients and instructs them to advise her on their specific goals and expectations.

"I can't tell you how many times I have looked at the patient on a consult, assessed precisely what I thought the ideal aesthetic outcome is, and then be told that it's actually something completely different that they are here for me to treat," Dr. Hirsch said at the annual meeting of the American Society of Cosmetic Dermatology and Aesthetic Surgery. "A mirror is your friend."

She went on to discuss other ways to avoid potential pitfalls:

► **Always snap before and after photographs.** "There are limited legal protections," said Dr. Hirsch, a dermatologist who practices in Cambridge, Mass. "Before-and-after photographs are one of the few things that will objectively capture accurate data."

► **Beware of unrealistic expectations.** "You need to know what unrealistic expectations are and not treat those people in the first place," she said. "You're not going to make them happy and you're going to make yourself miserable in the process."

► **Assess for medical contraindications.** These include history of hypersensitivity or allergy to known filler ingredients, history of oral herpes simplex virus and keloids, and any problems with scarring. "In my office, we check for these problems three times," said Dr. Hirsch, who is the immediate past president of the ASCDAS. "And it is remarkable how many people neglect to mention these critical points until being asked repeatedly."

► **Make sure patients can afford the services required for the outcome desired.** Be wary of patients who require three syringes of product for optimal results, yet only want to pay for one.

► **Have patients fill out a consent form during every visit.** Nothing is more important to the aesthetic physician than informed consent, she emphasized. "I am surprised every time I hear a physician say, 'I use the consent form that came with the job.' Should complications arise, it is critical that this has been done properly to protect yourself."

Describing her own consent forms, she noted, "It's not

enough that patients sign at the very bottom of removed pages of small print. They have to sign next to each potential complication and initial it. It has to be witnessed by someone and time stamped. These are critical aspects." She advised checking with an attorney for the best relevant advice.

► **Educate patients about common side effects.** To help reduce the occurrence of purpura, Dr. Hirsch advises patients to eat a lot of pineapple preprocedure, because it contains bromelain. Another option is to take five tablets of arnica, a substance commonly used for muscle pain and bruising, the night before the procedure and another five on the day of the procedure.

Other ways to minimize bruising include applying pressure during and immediately following the injections, using topical anesthesia, mixing the filler with collagen products to stabilize platelets, adding a lidocaine wash to injectables that do not contain an anticoagulant, and using the "push ahead" technique, whereby you get the needle tip to the plane and extrude the needle ahead of the tip. By using this technique, which Dr. Hirsch attributes to Dr. Jean Carruthers, one allows the product rather than the sharp edge of the needle to create the injection plane for the product, thereby reducing tissue trauma (*Dermatol. Surg.* 2005;31:1604-12).

Should evidence of infection develop after the procedure, incise and drain the abscess as rapidly as possible. Culture the patient for both routine and atypical bacteria and prescribe a course of empiric antibiotics followed by specific antibiotics. "Follow up on those cultures," Dr. Hirsch advised.

If blanching or pain occurs at the injection site, stop immediately, because this can be the only sign of an impending vascular injury. Immediate administration of heat, massage, and nitroglycerin paste helps minimize or reverse permanent injury. A recent case report demonstrated that immediate administration of hyaluronidase can also be of great value (*J. Drugs Dermatol.* 2007;6:325-8). Once the vascular accident is managed, consider treatment with a pulsed-dye laser or intense pulsed light to improve discoloration.

Dr. Hirsch had no conflicts to disclose relevant to her presentation. ■

By Doug Brunk, *Elsevier Global Medical News*. Reprinted from *Skin & Allergy News*, February 2009.

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Single Laser Tx Reduced Perioral Wrinkles

A single treatment with a microfractional 2940-nm erbium:YAG laser resulted in perioral wrinkle reduction of greater than 40% and an improvement of 2-3 grades on the Fitzpatrick wrinkle assessment scale in a recent study.

In all, 23 patients with a score of 5-9 on the 9-point Fitzpatrick scale underwent full-face laser treatment. The improvements from baseline were noted after the first treatment, Dr. E. Victor Ross reported at the annual meeting of the American Society for Laser Medicine and Surgery.

The patients, who had skin types ranging from I-III, were treated with a 6- to 10-mm spot size and energy ranging from 400-920 microbeams/cm². Between one and three passes were used in less photodamaged areas, and three to eight passes were used in more severely damaged areas. Additionally, small areas were treated with a traditional short-pulse erbium:YAG laser at four passes and 5 J/cm² to allow comparison of wound healing time and clinical end points between the two lasers.

Preliminary findings suggest that the microfractional erbium:YAG treatments resulted in a similar wrinkle response to that observed with traditional short-pulse erbium:YAG laser treatments; however, healing times were reduced with the microfractional erbium:YAG, said Dr. Ross of the Scripps Clinic in San Diego.

Dr. Ross acknowledged that he has received equipment, consulting fees, and a research grant from Palomar Medical Technologies Inc.

"There was very rapid recovery, both histologically and clinically," he said, noting that the average full-face treatment time was 48 minutes. Re-epithelialization of the basal layer of the epidermis occurred within 12-24 hours, and complete re-epithelialization occurred within 4-5 days.

Bronzed skin was noted immediately after the treatments, and some patients experienced focal pinpoint hemorrhage. At 2 weeks, however, only mild erythema remained, he said.

On microscopic examination, separated columns of ablation were noted, typically with a depth of 200 microns and 20-30 microns of residual thermal damage at the periphery of the conical microwounds. Not only did the treatment lead to smoothing of the skin and reduction of perioral wrinkles, but improvements in dyschromia were also noted, Dr. Ross said.

Although optimal treatment parameters for wrinkle reduction remain to be defined, these findings suggest that microfractional 2940-nm laser treatment is superior to traditional short-pulse erbium:YAG laser treatment for this purpose. ■

By Sharon Worcester, Elsevier Global Medical News. Reprinted from Skin & Allergy News, June 2008

Fractional Laser Therapy Found Effective for Hands

Nonablative fractional laser therapy applied at conservative settings achieved moderate global improvement in photodamaged hands in a pilot study.

Six months following last treatment sessions, 8 of 10 patients in the study showed a 26%-50% improvement in wrinkles, pigmentation, and skin texture, based on a formal investigator-rated scoring system, Dr. Neil S. Sadick reported at the annual meeting of the American Academy of Cosmetic Surgery.

The results improved from 1-month post treatment to the 6-month follow-up mark, Dr. Sadick noted. The treatment sessions were well tolerated, side effects were mild and self-limited, and return to daily activities was immediate, said Dr. Sadick, a dermatologist at Cornell University, New York, and immediate past president of the Cosmetic Surgery Foundation.

The 10 patients (mean age, 57 years) were Fitzpatrick skin types I-III. Their bilateral photodamage on the dorsum of the hands was treated with a fractional 1550-nm erbium-doped fiber laser, the first-generation Fraxel laser marketed by Reliant Technologies Inc.

Patients underwent five or six treatment sessions 3-4 weeks apart, with topical anesthesia. The laser energy setting was 6 mJ at the first session, increasing as tolerated by 2 mJ at each subsequent session. The total microthermal zone density was 1,000-2,000/cm².

The technique used in treating the hands was the same as

with Fraxel therapy on the face, with three or four passes per session being done. All patients had immediate posttreatment erythema. Unlike on the face, where it resolves within a day or two, the erythema on the hands lasted for as long as 4 weeks.

Half of the patients developed mild edema. This was most prominent after the first treatment session. Patients reported that the discomfort associated with treatment was mild but increased slightly with increasing laser energy.

Three patients underwent biopsies at baseline and again 3 and 6 months after their last session. Histologic evaluation using hematoxylin and eosin and elastin tissue stains showed a treatment-related decrease in atypical keratinocytes, increased rete ridge formation in the epidermis, enhanced collagen density in the epidermis and papillary and reticular dermis, improvement in the baseline irregular dermal architecture, and reduced solar elastosis. There was no histologic evidence of scarring or inflammatory changes.

Dr. Sadick disclosed that he performed his pilot study for Reliant in return for discounted equipment. He is on the speakers bureaus for laser and medical device manufacturers Cynosure, Palomar Medical Technologies Inc., Syneron Medical Ltd., and Cutera Inc. ■

By Bruce Jancin, Elsevier Global Medical News. Reprinted from Skin & Allergy News, March 2009

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Photos courtesy of Dr. William Baugh and Dr. Joe Niamtu



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